UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF NEW YORK

SECURITIES AND EXCHANGE COMMISSION, Plaintiff, v. BIOVAIL CORPORATION, EUGENE MELNYK, BRIAN CROMBIE, JOHN MISZUK, and KENNETH HOWLING, Defendants.	No. 08-cv-02979 (LAK) (GWG) ECF Case

DEFENDANT BRIAN CROMBIE'S MEMORANDUM OF LAW IN SUPPORT OF HIS MOTION TO DISMISS THE AMENDED COMPLAINT UNDER FED. R. CIV. P. 9(b)

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Defendant Brian Crombie respectfully submits this memorandum of law in support of his motion to dismiss the amended complaint under Fed. R. Civ. P. 9(b) for failure to allege facts that give rise to a strong inference of scienter.

PROCEDURAL HISTORY

The Securities and Exchange Commission filed its original complaint in this case on March 24, 2008. The original complaint contained numerous conclusory allegations and failed to satisfy the heightened pleading requirements for fraud under Rule 9(b). In light of the complaint's inadequacies, Mr. Crombie and two other defendants filed motions to dismiss on June 23, 2008. The SEC, in an effort to cure the pleading deficiencies highlighted by those motions, filed its amended complaint on July 31, 2008 (attached as Exhibit A to the Chen Decl.). Despite having the benefit of the defendants' motions as roadmaps, however, the SEC failed to remedy many of the fundamental defects in its original complaint and still has not alleged sufficient facts to support a strong inference of scienter.

PRELIMINARY STATEMENT

In its second bite at the apple, the SEC has had another opportunity to marshal all the facts that it acquired during its lengthy investigation of Biovail Corporation, Inc. ("Biovail") and its executives. The SEC has investigated this matter for over four and a half years. In concert with its Canadian counterpart, the Ontario Securities Commission, the SEC has subpoenaed millions of pages of documents and compelled testimony from dozens of witnesses, including Mr. Crombie, who testified on three separate occasions. Despite the SEC's far-reaching and lengthy investigation, which encompassed discovery well beyond what would have been permitted by the Federal Rules of Civil Procedure, the SEC's amended complaint still falls well short of the basic pleading standards required for cases alleging fraud. See Fed. R. Civ. P. 9(b).

The gist of the SEC's amended complaint is that Mr. Crombie and others allegedly made false statements or caused Biovail to make false statements to the investing public and to the company's independent auditors. The amended complaint repeatedly bandies about the words "fraud," "sham," and "phony," and, on numerous occasions, makes the broad assertion that Mr. Crombie "knew" or "recklessly disregarded" that certain public statements or representations were "materially false and misleading." Stripping away those pejoratives and conclusory allegations, however, one finds a paucity of concrete *facts* to support the SEC's claims of fraud.

With respect to two of the so-called "accounting schemes," see Amended Compl. ¶ 2, the PharmaTech arrangement and the "bill-and-hold" transaction, see Amended Compl. ¶¶ 54-89, 90-133, the amended complaint fails to plead facts demonstrating a "strong inference of scienter." See ATSI Communications, Inc. v. Shaar Fund, Ltd., 493 F.3d 87, 99 (2d Cir. 2007); SEC v. Collins & Aikman Corp., 524 F. Supp. 2d 477, 488 (S.D.N.Y. 2007) ("the SEC is subject to Rule 9(b) and must therefore plead a 'strong inference' of scienter"). The SEC alleges no facts to indicate that Mr. Crombie had a concrete "motive and opportunity" to commit fraud. Nor does the amended complaint contain "strong circumstantial evidence" of conscious misbehavior or recklessness on his part.

Instead, the amended complaint alleges that Biovail made improper accounting judgments (at least in the view of the SEC) and that Mr. Crombie somehow *must* have known that those judgments were incorrect – even though there are few allegations that he was told by anyone or shown any documents to that effect. See Shields v. Citytrust Bancorp, Inc., 25 F.3d 1124, 1129 (2d Cir. 1994) (rejecting notion of "fraud by hindsight"); Denny v. Barber, 576 F.2d 465, 470 (2d Cir. 1978). Because there are insufficient allegations under Rule 9(b) to support a claim of fraud, the amended complaint should be dismissed.

FACTUAL BACKGROUND[1]

Biovail is a publicly traded pharmaceutical company based in Ontario, Canada. Amended Compl. ¶ 1. During the relevant period, from May 2000 to August 2004, Mr. Crombie served as Biovail's Chief Financial Officer ("CFO") and, from August 2004 to May 2007, he was Senior Vice President for Strategic Development. Amended Compl. ¶ 14. The SEC appropriately does not allege that Mr. Crombie is a certified public accountant in the United States or a chartered accountant in Canada. Nor does the SEC claim that Mr. Crombie has any specialized training in U.S. (or Canadian) generally accepted accounting principles ("GAAP") or any other accounting system.

The SEC's amended complaint asserts that Mr. Crombie was involved in three matters that were the subject of false or misleading statements regarding Biovail's financial results: (1) public statements regarding a shipment of Wellbutrin XL involved in a fatal truck accident on October 1, 2003 and its effect on Biovail's reported revenue for the third quarter of 2003, Amended Compl. ¶¶ 17-53; (2) an alleged failure to record expenses and liabilities in 2001 and 2002 incurred by a separate entity, Pharmaceutical Technologies, Corp. ("PharmaTech"), which conducted research and development ("R&D") on six Biovail products, id. ¶¶ 54-89; and (3) Biovail's recognition of revenue from the sale of Wellbutrin XL to a distributor in a "bill-and-hold" transaction in the second quarter of 2003, id. ¶¶ 90-133.[2] This motion addresses the

[1] For purposes of this motion to dismiss, well-pleaded facts in the amended complaint are assumed to be true, see In re NYSE Specialists Sec. Litig., 503 F.3d 89, 95 (2d Cir. 2007); however, this Court need not accord "[l]egal conclusions, deductions or opinions couched as factual allegations . . . a presumption of truthfulness." Id. (internal quotations omitted). The Court "may [also] consider any written instrument attached to the complaint, statements or documents incorporated into the complaint by reference, legally required public disclosure documents filed with the SEC, and documents possessed by or known to the plaintiff and upon which it relied in bringing the suit." ATSI, 493 F.3d at 98.

[2] The SEC also makes allegations concerning two other matters unrelated to Mr. Crombie – purported material misstatements regarding an unrecognized foreign exchange loss and the alleged failure by another executive to disclose properly his share ownership in Biovail. Amended Compl. ¶¶ 134-55.

insufficiency of the SEC's allegations regarding the PharmaTech arrangement and the bill-and-hold transaction.

The amended complaint attempts at the outset to allege Mr. Crombie's and others' purported motive for engaging in securities fraud. The SEC claims that Biovail's executives were "[o]bsessed with meeting quarterly and annual earnings guidance" in order to hide losses and "conceal the Company's poor performance." Amended Compl. ¶ 1. The SEC does not claim that Mr. Crombie sold any of his Biovail shares at inflated prices or received any other form of concrete benefit as a result of his alleged misconduct. At most, the amended complaint contends that Mr. Crombie's "compensation . . . had salary and bonus components. His bonus was dependent on several factors, including whether the Company met certain financial targets." Id. ¶ 14. Yet the SEC fails to allege that any of the purported fraudulent conduct had the actual effect of increasing Mr. Crombie's bonus. See Shields, 25 F.3d at 1130 ("Incentive compensation can hardly be the basis on which an allegation of fraud is predicated.") (quoting Ferber v. Travelers Corp., 785 F. Supp. 1101, 1107 (D. Conn. 1991)).

A. The PharmaTech Arrangement

PharmaTech was a separate company that provided R&D services to Biovail for a number of Biovail's pipeline products. PharmaTech was incorporated in Barbados on June 29, 2001, Amended Compl. ¶ 62, with an initial investment of $1 million by its sole shareholder, id. ¶ 55.[3] On the same day, PharmaTech and Biovail entered into several agreements under which PharmaTech would conduct the R&D related to six Biovail products in exchange for future

[3] The SEC alleges that Biovail "secured" PharmaTech's sole shareholder. Amended Compl. ¶ 55. Although it is not clear what the SEC means by the term "secured," the amended complaint does not allege that PharmaTech's shareholder lacked independence from Biovail. In particular, the SEC does not allege that PharmaTech's shareholder had any affiliation with Biovail, was controlled or directed by Biovail, or had any pecuniary interests in Biovail that would have affected his independence as a shareholder in PharmaTech.

royalty payments from Biovail, if those products proved in the future to be commercially successful. Id. ¶¶ 62-68 (discussing three agreements between PharmaTech and Biovail, including the Product Development and Royalty Agreement ("PDRA") (attached as Exhibit B to the Chen Decl.)).

To enable PharmaTech to conduct the R&D, Biovail provided PharmaTech with a non-exclusive, limited license to use Biovail's FlashDose and controlled release technologies "to develop the [six] products." Amended Compl. ¶¶ 62, 66, 71.[4] Under that non-exclusive license, Biovail retained ownership of its technologies at all times and could license it to others; however, PharmaTech was barred from using those technologies for any other purpose. See Exhibit B, PDRA § 3.1 (prohibiting PharmaTech from sub-licensing Biovail's technologies without Biovail's written consent); id. § 3.3 ("Nothing herein is intended to give [PharmaTech] any ownership of, interest in or assignment of any of the [FlashDose] Technology or [controlled release] Technology, except in accordance with the license and rights granted to [PharmaTech] by this Agreement.").

All costs and expenses associated with the R&D were to be paid for by PharmaTech, which could use funds drawn from a line of credit between PharmaTech and a lending institution (referred to in the amended complaint as the "Bank"). Amended Compl. ¶¶ 62, 71. The Bank's line of credit to PharmaTech was subject to annual renewal by the Bank, which could grant or deny the renewal in its sole discretion. Id. ¶ 71. As collateral, PharmaTech pledged to the Bank a security interest in the PDRA, including potential future royalty payments, as well as the *limited*

[4] Biovail's FlashDose technology provided for faster release of active ingredients by having the product dissolve rapidly on the user's tongue. Amended Compl. ¶ 66. Its controlled release technology "allowed for the gradual and predictable release of active ingredients over twelve or twenty four hours." Id.

license to use Biovail's proprietary technologies. Id. In other words, in the event of a default by PharmaTech, the Bank could step into PharmaTech's shoes and assert its rights under the PDRA.

PharmaTech faced significant financial risks in attempting to develop a commercially viable product. There was a meaningful likelihood that the R&D process would prove to be unsuccessful. In June 2001, nobody knew whether Biovail's technologies "could be combined effectively and safely with any of the products in the PharmaTech portfolio." Amended Compl. ¶ 67.[5] Moreover, even if PharmaTech's scientific R&D proved to be fruitful, there was further uncertainty as to whether any drug would receive FDA approval, whether it would be cost-effective to manufacture and sell, and whether it would be commercially feasible in a competitive marketplace. If (and only if) the R&D were successful and led to a marketable drug, then Biovail would pay a royalty to PharmaTech based on a percentage of net sales over ten years. Id. ¶ 63. In addition, depending on future developments, Biovail had an option to purchase PharmaTech outright by paying a lump sum to PharmaTech's sole stockholder in exchange for all of his shares. Id. ¶ 68. That lump sum ranged from $1.25 million to $5 million, depending on when the option was exercised. Id.

If the R&D were unsuccessful or if the PharmaTech portfolio were unmarketable for any number of other reasons, then Biovail would have no obligation to make any royalty payments. Nor would Biovail have any financial incentive to exercise its option to purchase PharmaTech. Indeed, it would be contrary to Biovail's financial self-interest to acquire a failed endeavor and become obligated to repay its debts. Instead, Biovail – since it still owned its controlled release

[5] In June 2001, several of the products in the PharmaTech portfolio, including Oxycodone, Paroxetine, and Zolpidem, were in Phase I development. See Exhibit B, PDRA Schedule 1.28. According to the Food and Drug Administration, Phase I development "includes the initial introduction of an *investigational new* drug into humans. . . . These studies are designed . . . to gain *early* evidence on effectiveness." U.S. Food and Drug Admin., Center for Drug Evaluation and Research Frequently Asked Questions, http://www.fda.gov/cder/about/smallbiz/faq.htm (last visited Aug. 22, 2008) (emphases added).

and FlashDose technologies, see Exhibit B, PDRA § 3.3 – could simply abandon the unsuccessful venture with PharmaTech and use its proprietary technologies to develop other, more promising drugs.

Arrangements like the one between PharmaTech and Biovail are not unusual, and U.S. GAAP expressly provides that, depending on various factors, a party (such as Biovail) that participates in an R&D arrangement through which it can obtain the results of R&D funded entirely by others (such as PharmaTech or the Bank lending funds to PharmaTech) is *not* required to record those R&D expenses and liabilities on its own books and records. See Amended Compl. ¶¶ 59-61 (discussing Statement of Financial Accounting Standards 68 ("FAS 68")).

One critical factor under FAS 68 is whether the party (i.e., Biovail) is obligated to repay any of the R&D funds provided by the other parties (i.e., PharmaTech or the Bank as its principal creditor) "regardless of the outcome of the research and development." Id. ¶¶ 59-60. In other words, the question is whether the expenses and liabilities properly belong with PharmaTech or should instead be attributable to Biovail. Where it is probable that repayment will occur "regardless of the outcome of the research and development," then the party is obliged to reflect any R&D expenses and liabilities in its own financial statements. Id. In this case, the SEC alleges that the requirements of FAS 68 were not met and that Mr. Crombie and Biovail deliberately failed to include PharmaTech's expenses and liabilities as Biovail's own, thereby distorting Biovail's financial statements related to the third quarter of 2001 through the year-end of 2002. Id. ¶¶ 58, 81-89.

The difficulty with the SEC's theory lies in the fact that Mr. Crombie expressly consulted with Biovail's independent auditors concerning the PharmaTech arrangement *prior to the*

transaction closing to ensure that the Company's proposed accounting treatment was permissible under FAS 68. Amended Compl. ¶ 74. The auditors provided a written opinion to that effect, namely, that Biovail was *not* required to reflect PharmaTech's expenses and liabilities on its own financial statements. Id. (discussing opinion letter); see also Letter from Ernst & Young LLP to Mr. Brian Crombie dated June 29, 2001 (attached as Exhibit C to the Chen Decl.). In so doing, the independent auditors reviewed drafts of all the agreements between Biovail and PharmaTech and PharmaTech and the Bank. Id. There is no allegation that any of those papers were doctored or falsified in any way.

In order to avoid the clear import of the auditor's opinion letter – which negates any scienter on the part of Mr. Crombie – the SEC alleges that the auditor's opinion was premised on various misrepresentations by Mr. Crombie. In particular, the SEC asserts that:

- Crombie told the auditors that Biovail's management did not believe that it was probable that Biovail would repay the amounts being advanced [regardless of the outcome of the R&D] and that the funding provided by others should not be recorded as a liability.

- Crombie told the auditors that Biovail had not provided any explicit or implicit undertakings to any parties involved in the transaction to repay all or a portion of the funds provided.

- Crombie told the auditors that Biovail's management did not currently believe that it was probable that it would choose to purchase the common shares of PharmaTech rather than incur any penalty [associated with the potential transfer of its proprietary technology to a third party].

Amended Compl. ¶ 75.[6]

[6] The SEC alleges that Mr. Crombie provided the auditors with certain information reflected in their opinion letter in a column entitled "Application to these facts." Amended Compl. ¶ 74; see Exhibit C, at 5. Because the opinion letter first lists the various factors mentioned in FAS 68 and then separately discusses their application to the PharmaTech transaction, it is necessary to include the bracketed language to place the SEC's snippets into their proper context.

The sole premise for the SEC's assertion that those statements were "materially false and misleading" is their supposed inconsistency with alleged oral statements that Mr. Crombie was making contemporaneously to the Bank. Amended Compl. ¶ 77. According to the amended complaint, Mr. Crombie supposedly told the Bank that: (1) "Biovail had a compelling business incentive to acquire PharmaTech and repay the loans because Biovail would want the royalties from any successfully developed products"; (2) "Biovail did not want its competitors acquiring access to the license to use the FlashDose . . . or controlled release technologies that Biovail had assigned to PharmaTech"; and (3) "the Bank had an effective 'annual put' to Biovail, meaning that, when the credit facility came up for review after one year, if the Bank declined to extend the financing, the Bank could expect Biovail to acquire PharmaTech and repay the indebtedness." Id. ¶ 73.[7]

There is no inconsistency between those two sets of alleged statements. The first statement to the Bank simply reflected the obvious hope on the part of Biovail and Mr. Crombie that the PharmaTech arrangement would yield one or more "successfully developed products," id., and, under those circumstances, Biovail would have a compelling incentive to exercise its option to acquire PharmaTech, rather than pay out royalties over the next ten years.[8] That statement provides no insight – one way or the other – into what Biovail might do if the R&D appeared unpromising.

[7] There is no description as to when, where, or to whom in particular these purported statements to "the Bank" were made. There is not even an indication whether all three statements were made during a single discussion with one Bank employee or in multiple discussions with different ones. To make matters even more confusing, the SEC's description of what precisely Mr. Crombie said to the Bank differs from one part of the complaint to the next. Compare Amended Compl. ¶ 73 with id. ¶ 77.

[8] Of course, if Biovail expected the drugs to be only marginally successful, then depending on the net present value of any royalty payments versus the cost of purchasing PharmaTech outright and repaying its debts, Biovail still might not have a compelling incentive to exercise its option.

Likewise, with respect to Mr. Crombie's third alleged statement to the Bank, the concept of an "effective annual put" meant only that, so long as Biovail and Mr. Crombie believed the R&D would be successful, then Biovail would, of course, act rationally to protect its anticipated upside. If Biovail continued to believe that PharmaTech's R&D would yield a viable product, then Biovail – like any other sponsor of such a product – would attempt to keep it alive by acquiring PharmaTech in the event that the lender of first resort declined to renew PharmaTech's financing. On the other hand, if PharmaTech's R&D appeared unpromising, then Biovail was always free to walk away from the arrangement and let PharmaTech default.

In other words, Mr. Crombie's first and third alleged statements merely express the obvious considerations that one could deduce from reviewing the contractual documents (all of which were fully shared with the auditors). They say nothing about Biovail's intentions if the R&D were to go sour. Absent that, nothing in Mr. Crombie's statements to the Bank points to a knowing violation of U.S. GAAP.

Only the second alleged statement by Mr. Crombie to the Bank – that Biovail did not want its competitors acquiring access to PharmaTech's license for its controlled release and FlashDose technologies – even remotely suggests that Biovail might exercise its option to acquire PharmaTech in the event that the R&D were unsuccessful. As alleged in the amended complaint, if PharmaTech defaulted and the Bank exercised its security interest in the PDRA, then the Bank could potentially assign those rights to another pharmaceutical company, a scenario that Biovail would prefer to avoid. Amended Compl. ¶ 77.

Yet that reluctance would create an incentive for Biovail to acquire PharmaTech if (and only if) those competitors were then expected to breach the terms of the license, which was limited solely for use "to continue development of the [six portfolio] products," id., and

unlawfully convert Biovail's technology for their own purposes. See Exhibit B, PDRA §§ 3.1, 3.3; accord Amended Compl. ¶ 71 (describing the Bank's security interest in the PDRA, including the license to use Biovail's technology "to develop the products," i.e., not for general usage). There is no allegation that Biovail's competitors were prepared to engage in the unlawful conversion of Biovail's intellectual property, or that Mr. Crombie expected that to be the case. Without more, Mr. Crombie's alleged statement reflects nothing more than an obvious truism – of course, no company wants to see its intellectual property shared with its competitors. That hardly means, though, that Biovail would act contrary to its financial self-interest and acquire a failed endeavor, when it could rely instead on its lawful contractual rights.

Importantly, all of these points that Mr. Crombie allegedly communicated to the Bank were not concealed from the auditors, but were in fact expressly considered by them. See Exhibit C. The auditors noted that PharmaTech would own the royalty rights and that Biovail "could simply manufacture and market the products and pay the royalty," rather than exercise its purchase option and repay the Bank. Id. at 6-7. The auditors also understood that the annual renewal mechanism meant that the "lender makes annual decisions on additional tranches of funding," which placed the continuation of PharmaTech's R&D in potential jeopardy each year. Id. at 7. And the auditors recognized that PharmaTech "does not and will not own any 'core technology,'" id., and thus PharmaTech's ability to use that technology for purposes "other than the development of the products stipulated" was "limited," id. at 2-3.

In the end, the auditors noted that this was "an area of significant management judgment." Id. at 7. In other words, given the complexity and unpredictability of so many different variables, U.S. GAAP did not compel a definitive conclusion one way or the other. See Thor Power Tool Co. v. Comm'r, 439 U.S. 522, 544, 99 S. Ct. 773, 787 (1979) (stating that GAAP is not a

"canonical" set of rules, but rather "tolerate[s] a range of 'reasonable' treatments, leaving the choice among alternatives to management"); SEC v. Caserta, 75 F. Supp. 2d 79, 91 (E.D.N.Y. 1999) (same).[9] Given this permissible range of reasonable accounting treatments, the SEC's complaint must allege *facts* to show that Mr. Crombie exercised his judgment in an intentional and fraudulent violation of GAAP. This it does not do.

B. The Bill-and-Hold Sale of Wellbutrin XL in the Second Quarter of 2003

In October 2001, Biovail entered into a development agreement (the "Agreement") with another pharmaceutical company (referred to in the amended complaint as the "Distributor"), under which Biovail would manufacture an anti-depressant called Wellbutrin XL ("WBXL") for sale to the Distributor. Amended Compl. ¶ 92. The Agreement provided that Biovail would sell identical pills to the Distributor under two different pricing structures: (1) "sample" product, which the Distributor would provide to doctors to be given to patients as a promotional tool, and (2) "trade" product, which the Distributor would sell at a commercial price. Id. Biovail would be paid for sample pills effectively at cost and for trade pills at a fixed percentage of the Distributor's net sales revenues. Id. ¶ 93.

The actual distribution of WBXL was contingent on the product receiving formal FDA approval, which was still pending as of mid-2003. See Amended Compl. ¶ 94. In April and May 2003, however, the Distributor requested that Biovail begin manufacturing WBXL pills even before formal FDA approval had been granted, so that the Distributor would have sufficient supplies of product on hand in anticipation of an immediate full-scale launch as soon as approval

[9] It adds little, if anything, for the SEC to allege that Mr. Crombie was aware of U.S. GAAP requirements because he was previously involved in Biovail's earlier R&D arrangements. See Amended Compl. ¶ 78. As the auditors noted, an accounting analysis under FAS 68 is highly fact-specific. See Exhibit C, at 5. There is no allegation here that Biovail's previous arrangements were identical or even similar to this one with PharmaTech. In any event, even to this date, Biovail's auditors have not required the Company to restate its financial statements with respect to the PharmaTech arrangement.

was granted. Id. ¶¶ 98-99. Yet Biovail had no incentive to produce WBXL pills solely for sale as sample product, since filling sample orders would take up Biovail's limited manufacturing capacity without generating any incremental income. Id. ¶ 100.

Accordingly, in June 2003, the Distributor agreed to place an order for trade product that was based on a fixed price, with no possibility of "downward reconciliation." Amended Compl. ¶¶ 101-02 (quoting portions of June 19, 2003 letter from Mr. Crombie to Distributor); Letter from Mr. Brian Crombie to Mr. Stan Hull dated June 19, 2003, at 1 (attached as Exhibit D to the Chen Decl.) ("[The Distributor's CEO] agreed that there would be no downward reconciliation of the invoice price."). The negotiations leading up to that order were documented in Mr. Crombie's June 19, 2003 letter. Id. (stating that "in June of 2002, representatives of Biovail had a meeting with [the Distributor], at which time we discussed Biovail's requirement to ship trade supplies of WBXL to you in Q2 of 2003. . . . It was our understanding that we had verbally agreed both on the timing of those shipments and the pricing of the product . . . ."). The next day, the Distributor issued a firm purchase order for 27.1 million pills of trade product. Amended Compl. ¶ 103.

As of late June 2003, Biovail had approximately 18 million pills that were fully manufactured. Amended Compl. ¶ 103. The SEC does not allege that these were non-existent or phantom pills. Since FDA approval was still pending, however, Biovail could not label the final packaging, so "the Distributor agreed to let Biovail hold the product" awaiting final FDA approval. Id. Biovail would then ship the packaged pills to the Distributor as soon as approval was granted. Until that time, Biovail earmarked and segregated the pills in its warehouse and, on June 30, 2003, invoiced the Distributor for the sale of those pills. Id. ¶¶ 103-04, 110. Biovail

also recognized $8 million in revenue associated with that sale in its financial statements and other disclosures related to the second quarter of 2003. Id. ¶¶ 116-26.[10]

The SEC acknowledges that, under U.S. GAAP, a company may properly recognize revenue from such a "bill-and-hold" transaction if certain criteria are met. See Amended Compl. ¶ 106 ("Under certain limited circumstances a company may recognize revenue even before it has shipped the product."); id. ¶ 107 (discussing Staff Accounting Bulletin No. 101 ("SAB 101")).[11] In this case, the SEC contends that two of those requirements were violated in that (1) there was no "fixed schedule for delivery," since the date of final FDA approval was not yet known on June 30, 2003, id. ¶ 104, and (2) Biovail had not undertaken a "real segregation" of the 18 million pills from the rest of its inventory because the segregated pills "constituted all of Biovail's inventory at that time." Id. ¶¶ 110-11.

First, it is not at all clear that U.S. GAAP requires delivery to be scheduled for a fixed calendar date. SAB 101 is a staff accounting bulletin, which, as the name connotes, is only an interpretation by the SEC staff of U.S. GAAP requirements.[12] Moreover, nothing in SAB 101 requires a fixed date; it uses an entirely different term – "fixed schedule for delivery." The amended complaint offers no basis for the SEC's more restrictive interpretation of SAB 101,

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[10] We understand the SEC is alleging that the 18 million pills should not have been classified as trade product as of June 30, 2003. Assuming, however, that classification was correct, there is no allegation that the revenue associated with those trade pills ($8 million) was inflated.

[11] According to the SEC, those requirements are: (a) the risk of ownership has transferred to the buyer, (b) the customer has made a fixed commitment to buy the goods, (c) the buyer requests that the transaction be completed on a bill and hold basis, (d) there is a fixed schedule for delivery of the goods to the buyer, (e) the seller has not retained any specific performance obligations, (f) the ordered goods have been segregated from the seller's inventory and not used to fill other orders, and (g) the goods are complete and ready for shipment. Amended Compl. ¶¶ 106-107.

[12] As SAB 101 notes: "The statements in the staff accounting bulletins are not rules or interpretations of the Commission, nor are they published as bearing the Commission's official approval. They represent interpretations and practices followed by the Division of Corporation Finance and the Office of the Chief Accountant in administering the disclosure requirements of the Federal securities laws." SEC Staff Accounting Bulletin No. 101: Revenue Recognition in Financial Statements, 64 Fed. Reg. 68936, 1999 WL 112290 (1999).

much less a basis for concluding that Mr. Crombie (or anyone else) was aware of that limitation. The amended complaint offers no basis for the inference that Mr. Crombie, a non-accountant with no specialized knowledge of SAB 101, would understand the phrase "fixed schedule" to exclude a fixed occurrence, such as the granting of final FDA approval.[13]

Second, the SEC's assertion that Biovail failed to segregate the sold goods because those 18 million pills constituted Biovail's entire WBXL inventory is a non-sequitur. Under SAB 101, the ordered goods must have been segregated from the seller's inventory. Amended Compl. ¶ 107. There is no requirement that the ordered goods be cordoned off in any particular manner. Thus, under a plain English reading of SAB 101, if an entire section of Biovail's warehouse were designated to hold only the sold WBXL, that would inherently segregate those goods from other inventory belonging to Biovail. There is no allegation the sold WBXL was commingled with Biovail's unsold products. In any event, even assuming that the SEC's reading of SAB 101 were correct, there is no allegation that Mr. Crombie was informed that the WBXL was "unsegregated."

The amended complaint acknowledges that, as of June 30, 2003, at the end of Biovail's second quarter, the Distributor had placed a firm order with Biovail for WBXL pills at a fixed price. Amended Compl. ¶ 103. Biovail had manufactured 18 million pills and earmarked them for the Distributor. Id. And as far as Mr. Crombie was aware, those pills had been sold at a fixed price, were segregated in Biovail's warehouse, and would be shipped to the Distributor

[13] Although the SEC alleges that Mr. Crombie "reviewed SAB 101 and understood the requirements under U.S. GAAP for a valid bill and hold transaction," Amended Compl. ¶ 109, the amended complaint does not allege that Mr. Crombie was aware of the SEC's purported interpretive gloss. (Most likely, this is because there is no published guidance to support the SEC's current interpretation.) Moreover, the fact that Mr. Crombie "did not discuss the bill and hold transaction with the Company's independent auditors at the time of the transaction," id., hardly supports a strong inference of fraud. If anything, the more plausible inference is that Mr. Crombie (perhaps mistakenly) assumed he could rely on a straightforward, plain English reading of SAB 101. See Random House Dictionary of the English Language 1276 (unabridged ed. 1967) (defining "schedule" as "a plan of procedure, usually written, for a proposed objective").

upon the granting of final approval by the FDA (or presumably discarded on the Distributor's instruction, if the FDA refused to grant approval). In other words, when the window closed on Biovail's second quarter, Mr. Crombie believed that all the requirements for a proper bill-and-hold transaction had been met, and the amended complaint is devoid of any allegations to the contrary.

The SEC's contention that Mr. Crombie was aware that "all of the tablets [that were sold on June 30] were already too old for trade use" is squarely contradicted by the SEC's own allegation (indeed, in the same sentence) that "*no one* knew prior to FDA approval what the exact expiration date for trade product would be." Amended Compl. ¶ 111 (emphasis added). If "no one" (a category that, by definition, included Mr. Crombie) knew exactly when the trade pills would become stale, it defies logic for Mr. Crombie to have known (somehow) that, on June 30, 2003, all 18 million pills were already too old. Indeed, it would be inherently implausible for "all of the tablets" – including some that were manufactured as late as June – to have become "too old" by June 30.[14]

In any event, when the FDA issued its final approval on August 29, 2003, see Amended Compl. ¶ 94, it provided for an expiration period of twelve months. See Approval Letter from Dr. Russell Katz, Director, Food and Drug Administration, to Mary E. Martinson, at 1 (attached as Exhibit E to the Chen Decl.). Thus, even WBXL pills manufactured in early 2003 could be packaged and sold as trade product in late 2003 without any serious concern about the pills going stale.

[14] There is no allegation that the Distributor had any concerns about the 18 million pills going stale. In other words, if the Distributor thought that staleness was an issue, it was explicitly taking that risk. Indeed, by placing an order and buying the pills before receiving FDA approval, the Distributor acted knowing it could be stuck with those pills for any number of reasons.

The SEC can only point to actions that allegedly took place *after* June 30, 2003 that purportedly violated U.S. GAAP.[15] The amended complaint alleges that, sometime in early or mid-July, Biovail engaged in a so-called "pills switch," whereby the segregated pills were "designated" for shipment as sample pills and later replaced by substitute pills. Amended Compl. ¶¶ 111-115. The SEC does not allege that this "designation" took place before the end of the second quarter. Id. ¶ 110 (alleging that sample designation occurred "very soon thereafter"); id. ¶ 111 (alleging that sample designation occurred "no later than mid-July"). In other words, at quarter-end, all of the 18 million segregated pills had been sold at a fixed price. The pills switch arose only afterwards – and, so long as the pills were switched out by the time the now-sample pills were *shipped* from the warehouse in August 2003 (which was Mr. Crombie's expectation), id. ¶ 112, there would always be 18 million pills remaining in the segregated section, ready for delivery as trade product.

The SEC's allegation – that there were insufficient replacement pills as of mid-July when the "designation" allegedly occurred – is beside the point. Amended Compl. ¶ 114. There is no allegation that Biovail recognized any sample revenue on the date of "designation." So there is no issue with Biovail recognizing both trade and sample revenue at a time when only one set of pills was in existence. In the absence of any contrary allegation, presumably, the sample revenue was recognized when the now-sample pills were shipped.[16]

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[15] Although the SEC alleges here that post-quarter-end actions should somehow relate back to alter the accounting for the past quarter, the SEC has alleged elsewhere that doing just that is *fraudulent and improper*. See SEC v. Computer Associates Int'l, Inc., Litigation Release No. 18891, 2004 WL 2109232 (Sept. 22, 2004) (alleging that defendant committed fraud by taking into account activities that occurred after quarter-end).

[16] In addition, the various mix-ups with the June and August invoices are irrelevant. Biovail issued invoices in June 2003 for the 18 million pills at the agreed-upon fixed price. Amended Compl. ¶ 104. After the pills switch occurred, when those 18 million pills were shipped in August 2003, Biovail issued additional invoices associated with those now-sample pills. Amended Compl. ¶ 120. All that needed to be done, however, was to amend the June invoices with an updated reference to the newly manufactured pills (which remained segregated in the Biovail warehouse awaiting FDA approval). And this is essentially what occurred when Biovail issued two credit memos

Fatal to the SEC's amended complaint is the lack of any allegation that Mr. Crombie knew the "pills switch" would violate U.S. GAAP. The SEC does not contend that Mr. Crombie reviewed any accounting literature or received any accounting guidance to indicate that a pills switch of the *same* product for the *same* customer would be impermissible. Nor is there any allegation that Mr. Crombie was informed that a pills switch of the *same* product for the *same* customer would result in a *post hoc* change under U.S. GAAP to the accounting for a quarter that had already ended.

Lastly, the SEC claims that Mr. Crombie made various material misstatements and omissions about the bill-and-hold transaction to the Company's independent auditors. Amended Compl. ¶¶ 127-33. In particular, the amended complaint alleges that, during the quarterly review for the second quarter of 2003, Mr. Crombie failed to correct the auditors' misunderstanding that the sale was a "shipment" rather than a bill-and-hold transaction and failed to inform the auditors about the pills switch. Id. ¶¶ 129, 132. There is no allegation, however, that Mr. Crombie created any misimpression on the part of the auditors – or was even aware that they had one. For example, the SEC does not allege that the auditors raised any questions to Mr. Crombie that would have prompted him to provide additional details. In the absence of such an allegation, it is more plausible to infer either that Mr. Crombie (perhaps mistakenly) assumed the auditors knew about those facts (and, for example, were using the term "shipment" loosely as a synonym for "transaction" or "sale") or that he failed to recognize their significance to the accounting

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canceling the June invoices and then re-issued new invoices with the updated information. Amended Compl. ¶¶ 124, 133. In the end, there is no allegation that Biovail attempted to double-bill the Distributor. At all times, there was only one set of invoices for the trade sale in June and one set of invoices for the sample sale in August. There is no allegation that, once the confusion was resolved, the Distributor still refused pay in full for 18 million pills at the fixed price.

treatment.[17] In addition, the SEC alleges that, during the year-end review for 2003, Mr. Crombie misled the auditors about the Distributor's refusal to pay the original June invoices and the need for Biovail to issue "credit memos" canceling those invoices (which were later re-issued with updated information for the new trade pills). Id. ¶¶ 130, 133. The amended complaint fails to allege, however, that Mr. Crombie was involved in (or even aware of) the issuance of the credit memos, id. ¶ 124, or that he had been told of the alleged "true" reason why they were issued. Accordingly, none of Mr. Crombie's statements to the auditors can give rise to an inference of scienter.

ARGUMENT

I. THE AMENDED COMPLAINT MUST BE DISMISSED BECAUSE THE PLAINTIFF FAILS TO ALLEGE FACTS THAT GIVE RISE TO A STRONG INFERENCE OF SCIENTER

Under Rule 9(b), any complaint that sounds in fraud must allege facts giving rise to a "strong inference of scienter." ATSI, 493 F.3d at 99. This requirement applies equally to the SEC as well as to private plaintiffs. See Collins & Aikman, 524 F. Supp. 2d at 488 ("the SEC is subject to Rule 9(b) and must therefore plead a 'strong inference' of scienter"); see also SEC v. Durgarian, 477 F. Supp. 2d 342, 353 (D. Mass. 2007) ("the SEC must also set forth facts giving rise to a 'strong inference' that the defendants acted with the required state of mind") (internal quotations omitted); SEC v. Boling, No. 06-1329, 2007 WL 2059744, at *4 n.1 (D.D.C. July 13, 2007).[18] The Second Circuit has cautioned that the requirements of Rule 9(b) must be "applied

[17] Notably, even after Biovail's independent auditors became aware of the bill-and-hold transaction, the lack of a fixed calendar date for delivery, and the pills switch, they have still not required Biovail to restate its financial statements from the second quarter of 2003 to remove the bill-and-hold revenue. That fact tends to negate any inference of fraudulent intent. See Druskin v. Answerthink, Inc., 299 F. Supp. 2d 1307, 1323 & n.25, 1326 (S.D. Fla. 2004) (stating that any inference of scienter was refuted because, among other things, there were "no restatements or auditor resignations").

[18] The Second Circuit has long held that all plaintiffs, including the SEC, are subject to Rule 9(b), see SEC v. Republic Nat'l Life Ins. Co., 378 F. Supp. 430, 439 (S.D.N.Y. 1974), including its requirement that a complaint

assiduously to securities fraud" to ensure against scurrilous allegations that might impugn a defendant's integrity. See Lentell v. Merrill Lynch & Co., 396 F.3d 161, 168 (2d Cir. 2005).

In order to qualify as "strong," an inference of scienter "must be more than merely 'reasonable' or 'permissible' – it must be cogent and compelling, thus strong in light of other explanations." Tellabs, Inc. v. Makor Issues & Rights, Ltd., 551 U.S. ---, 127 S. Ct. 2499, 2510 (2007). "The strength of an inference cannot be decided in a vacuum." Id. Thus, the Supreme Court has instructed that this court "must consider plausible nonculpable explanations for the defendant's conduct." Id. at 2502.[19]

As a general matter, a strong inference of scienter may be shown only where there are well-pleaded facts either (1) demonstrating that Mr. Crombie had the "motive and opportunity" to commit fraud, or (2) constituting "strong circumstantial evidence" of conscious misbehavior or extreme recklessness. See Collins & Aikman, 524 F. Supp. 2d at 487. Conclusory allegations of fraudulent intent are wholly insufficient. Shields, 25 F.3d at 1129 (rejecting notion of alleging "fraud by hindsight"); Denny v. Barber, 576 F.2d 465, 470 (2d Cir. 1978) (same).

Moreover, where the SEC contends that a defendant "had access to contrary facts," the complaint must "specifically identify the reports or statements containing this information." Novak v. Kasaks, 216 F.3d 300, 309 (2d Cir. 2000); Collins & Aikman, 524 F. Supp. 2d at 485 (same); accord Goplen v. 51job, Inc., 453 F. Supp. 2d 759, 768 (S.D.N.Y. 2006) (stating that

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must plead facts to support a strong inference of scienter. See Shields, 25 F.3d at 1128. When Congress passed the Private Securities Litigation Reform Act ("PSLRA") in 1995, it codified the "strong inference" requirement for pleading fraud in securities actions brought by private plaintiffs. See 15 U.S.C. § 78u-4(b)(2). The PSLRA, however, did not alter the Rule 9(b) pleading standard in the Second Circuit. Collins & Aikman Corp., 524 F. Supp. 2d at 488-89. Thus, although the SEC is not directly subject to the PSLRA, it continues to be subject to Rule 9(b) and must therefore meet the "strong inference" standard. Id.

[19] Although the Supreme Court in Tellabs was addressing the statutory "strong inference" provision in the PSLRA, its general discussion on how to weigh the strength of an inference applies equally here under Rule 9(b). See Boling, 2007 WL 2059744, at *6.

boilerplate allegations of scienter are insufficient where plaintiffs "fail to identify any documents, meetings, or reports that show that the defendants knew or should have known" about contrary information).[20]

A. The Amended Complaint Does Not Allege that Mr. Crombie Had the Motive and Opportunity to Commit Fraud

To demonstrate "motive and opportunity" sufficient to satisfy Rule 9(b), the SEC must allege that the fraud was expected to lead to "concrete benefits" for the defendant. See Kalnit v. Eichler, 264 F.3d 131, 139 (2d Cir. 2001). "Motives that are generally possessed by most corporate directors and officers do not suffice; instead, plaintiffs must assert a concrete and personal benefit to the individual defendants resulting from the fraud." Id. Non-concrete motives, such as "the desire for the corporation to appear profitable" or "the desire to keep stock prices high to increase officer compensation" are inadequate. Id. Such allegations are "common to all corporate executives and, thus, too generalized to demonstrate scienter." Id.; see also SEC v. Todd, No. 03-2230, 2007 WL 1574756, at *12 (S.D. Cal. May 30, 2007) (stating that scienter cannot be established based on the "desire of a corporate officer to generate revenue and meet analyst expectations"); In re Northern Telecom Ltd. Sec. Litig., 116 F. Supp. 2d 446, 462 (S.D.N.Y. 2000) ("The absence of stock sales by insiders, or any other evidence of pecuniary gain by company insiders at shareholders' expense, is inconsistent with an intent to defraud shareholders.").

[20] See also Caiafa v. Sea Containers Ltd., 525 F. Supp. 2d 398, 413 (S.D.N.Y. 2007) ("[P]laintiffs must specifically allege[] defendants' knowledge of facts or access to information contradicting their public statements.") (internal quotations omitted); In re Bristol-Myers Squibb Sec. Litig., 312 F. Supp. 2d 549 (S.D.N.Y. 2004) (same); Malin v. XL Capital Ltd., 499 F. Supp. 2d 117, 140 (D. Conn. 2007) ("the plaintiff's allegations, based on confidential witness reports, that information was 'known' or 'common knowledge' within the Company were too vague and conclusory to support a finding that the defendants knew or were severely reckless in not knowing that they were making false statements").

In this case, the SEC makes only generalized allegations with respect to Mr. Crombie's supposed desire to conceal Biovail's poor performance and to meet earnings targets. Amended Compl. ¶ 1. The claim that Mr. Crombie's "bonus was dependent on several factors, including whether the Company met certain financial targets" fares no better. Id. ¶ 14.[21] That allegation is no different from ones that have been repeatedly rejected by any number of courts. E.g., Shields, 25 F.3d at 1130 ("Incentive compensation can hardly be the basis on which an allegation of fraud is predicated.") (quoting Ferber v. Travelers Corp., 785 F. Supp. 1101, 1107 (D. Conn. 1991)); In re Bristol-Myers Squibb Sec. Litig., 312 F. Supp. 2d 549, 561 (S.D.N.Y. 2004) (rejecting argument that "performance-based compensation [was] evidence of motive sufficient to support a strong inference of scienter").[22] Because the only motive alleged here is one that applies to nearly every corporate officer – namely, that Mr. Crombie's pay was tied (in some indefinite way) to the Company's performance – the SEC cannot meet its obligations under Rule 9(b) through the "motive and opportunity" prong.

B. The Amended Complaint Does Not Allege Sufficient Facts Showing Strong Circumstantial Evidence of Conscious Misbehavior or Recklessness

In the alternative, the SEC may show a "strong inference" of scienter by pointing to "strong circumstantial evidence" that Mr. Crombie engaged in fraudulent or reckless misconduct. Yet where, as here, "motive is not apparent . . . the strength of the circumstantial allegations must be correspondingly greater." Kalnit, 264 F.3d at 142 (internal quotations omitted). "At the

[21] Especially with respect to the bill-and-hold transaction, which, at most, had the effect of shifting revenue from the third quarter of 2003 into the second quarter of 2003, there was no effect whatsoever on the Company's overall year-end performance and, therefore, no conceivable effect on Mr. Crombie's year-end bonus.

[22] See also In re Cerner Corp. Sec. Litig., 425 F.3d 1079, 1085 (8th Cir. 2005) (holding that allegations about defendants' "desire to increase their bonus and executive compensation packages and to make the company seem more profitable . . . fail to raise the requisite strong inference of scienter"); SEC v. Guenther, 395 F. Supp. 2d 835, 848 (D. Neb. 2005) (holding that SEC failed to establish facts supporting inference of scienter where there was no evidence that defendants "made any money" from alleged fraud).

least," the SEC must point to "*conduct* which is highly unreasonable and which represents an extreme departure from the standards of ordinary care to the extent that the danger was either known to the defendant or so obvious that the defendant must have been aware of it." Id. (emphasis added) (internal quotations omitted).

Even clear violations of U.S. GAAP, standing alone, do not establish that the defendant acted with the requisite intent to defraud. See In re BISYS Sec. Litig., 397 F. Supp. 2d 430, 448 (S.D.N.Y. 2005) (Kaplan, J.); see also Chill v. General Electric Co., 101 F.3d 263, 270 (2d Cir. 1996) (holding that allegations of GAAP violations "without corresponding fraudulent intent" do not suffice to state securities fraud claim). This is because an innocent misapplication of complex accounting principles, rather than deliberate deceit, is just as likely, if not more likely, to be the cause.

Finally, boilerplate allegations of scienter – for example, that the defendant "'knew but concealed' some things, or 'knew or [was] reckless in not knowing' other things" – are insufficient to withstand dismissal under Rule 9(b). Shields, 25 F.3d at 1129. Such allegations are "so broad and conclusory as to be meaningless." Id. (internal quotations omitted); see also Decker v. Massey-Ferguson, Ltd., 681 F.2d 111, 114 (2d Cir. 1982) ("conclusory allegations that defendant's conduct was fraudulent or deceptive are not enough"). In this case, after putting aside the SEC's repeated "conclusory" and "meaningless" allegations, see, e.g., Amended Compl. ¶¶ 81, 82, 83, 87, 89, 117, 119, 121, 123, 125, 126, one is left with a paucity of actual *facts* to support an inference of scienter.

Regarding the PharmaTech arrangement, the SEC's complaint boils down to a purported divergence between the statements Mr. Crombie allegedly made to the auditors versus what he supposedly said to the Bank. As explained above, however, see pp. 11-14, supra, there is no

inconsistency between those two sets of alleged statements. Mr. Crombie never told the Bank it was probable that Biovail would acquire PharmaTech and repay the Bank *regardless of the outcome of the R&D*. At most, he allegedly said that Biovail had a compelling business interest to acquire PharmaTech "*because Biovail would want the royalties from any successfully developed products*." Amended Compl. ¶ 73 (emphasis added). Inherent in that statement, of course, is the contrapositive that, if PharmaTech's R&D efforts fell through and there were *no* "successfully developed products," then Biovail would have no compelling business interest to acquire PharmaTech.

Likewise, Mr. Crombie's alleged statement about the Bank having an "effective annual put" would only have served to reiterate the obvious – that Biovail expected the R&D to be successful and, if the Bank withdrew its financing, then Biovail would act rationally to protect its anticipated upside. It was not any sort of promise that Biovail would step in regardless of the circumstances. If anything, the opposite would be true – as would be clear to anyone listening. It would be economically irrational for Biovail to acquire a failed endeavor and become obligated to repay its debts.

Thus, the SEC is left with only one supposed statement that might reflect Mr. Crombie's view of Biovail's intentions regardless of the outcome of the R&D, namely, that "Biovail did not want its competitors acquiring access to the license to use [Biovail's proprietary] technologies." Amended Compl. ¶ 73. Again, aside from being an obvious truism, that fact would still not provide a compelling incentive for Biovail to acquire PharmaTech unless the alternative acquirer intended to breach its express contractual obligations, see Exhibit B, PDRA §§ 3.1, 3.3, and unlawfully convert Biovail's technologies to some unlicensed use – hardly the sort of contingency that Biovail would expect to occur.

In any event, the auditors were fully aware of the competing considerations that Biovail might have to consider. See Exhibit B, at 7 ("This is an area of significant management judgment."); see also Thor Power Tool, 439 U.S. at 544, 99 S. Ct. at 787 (GAAP tolerates "a range of 'reasonable' treatments, leaving the choice among alternatives to management"); SEC v. Caserta, 75 F. Supp. 2d 79, 91 (E.D.N.Y. 1999) (same); cf. Shalala v. Guernsey Memorial Hosp., 514 U.S. 87, 101, 115 S. Ct. 1232, 1239 (1995) ("There are 19 different GAAP sources, any number of which might present conflicting treatments of a particular accounting question."). The more plausible inference here is that Mr. Crombie was simply raising those same considerations with the Bank. Nothing in the amended complaint demonstrates that Mr. Crombie had reached a fixed or even probable determination that Biovail would exercise its option to purchase PharmaTech, regardless of the outcome of the R&D. In the absence of that allegation, there is no basis to infer that Mr. Crombie was deliberately hiding something that the auditors did not already know.

Regarding the bill-and-hold transaction, any strong inference of scienter rises or falls on the implications to be drawn from the SEC's two alleged inconsistencies with SAB 101. As explained above, however, see pp. 15-22, supra, the facts do not show that Mr. Crombie intentionally or even recklessly violated U.S. GAAP. First, with respect to the "fixed schedule for delivery": Even assuming that phrase requires a fixed *date* and prohibits a fixed *event* for delivery (a dubious assumption the SEC will be hard-pressed to prove at trial), the amended complaint still fails to allege facts showing that Mr. Crombie deliberately or recklessly ignored that bit of GAAP arcana. It is far more plausible that any alleged breach of that supposed prerequisite was the result of an inadvertent and innocent misunderstanding of U.S. GAAP by a non-accountant.

Second, with respect to the ordered goods being "segregated from the seller's inventory" and not being subject to fill other orders: The SEC does not allege that the 18 million pills in existence in late June were commingled with unsold inventory, or that Mr. Crombie was informed that was the case. Moreover, the allegation that Mr. Crombie somehow knew that all 18 million tablets were "already too old for trade use" is contradicted by the SEC's own statement that "*no one*" knew "what the exact expiration date for trade product would be." Amended Compl. ¶ 111 (emphasis added). Thus, the amended complaint demonstrates that, on June 20, 2003, the Distributor placed an order for more than 18 million pills at a fixed price with no possibility of downward reconciliation (meaning the Distributor was obliged to pay for those pills regardless of future contingencies) and, as of June 30, 2003, 18 million pills had been irrevocably sold to the Distributor under that agreement. Amended Compl. ¶¶ 103-04.

The fact that the pills switch took place does not undercut that conclusion.[23] The amended complaint does not allege that U.S. GAAP expressly prohibits the replacement of product being held as part of a bill-and-hold transaction, especially in light of the fact that both sets of product were sent to the *same* customer. And even if it did, there is no reason to infer that Mr. Crombie was aware of any such prohibition. In the end, the 18 million original pills were purchased by the Distributor at a fixed price in June, and the replacement pills were purchased at a lower sample price in August (and thereafter). Surely U.S. GAAP permits the owner of a product to use it for whatever purposes it wants. SAB 101 does not address this scenario, and the SEC does not allege that Mr. Crombie received any additional guidance or reviewed any other documentation advising him this was impermissible. See Collins & Aikman, 524 F. Supp. 2d at

[23] The SEC's reliance on later events, such as the pills switch or the updated invoices, to infer that this "must" have been what Mr. Crombie intended all along is precisely the sort of "fraud by hindsight" that has been rejected by courts. See Shields, 25 F.3d at 1129 (rejecting notion of "fraud by hindsight"); Denny, 576 F.2d at 470.

485 (stating that where SEC contends that defendant had access to contrary facts, complaint must "specifically identify the reports or statements containing this information") (internal quotations omitted); accord Goplen, 453 F. Supp. 2d at 768. And if that is so, then the SEC's case centers on a technical reading of an arcane accounting issue. This is not enough to support a strong inference of scienter.

Finally, it is notable that Biovail's independent auditors have never required the Company to restate its financial statements from the second quarter of 2003, even after they became aware of the terms of the bill-and-hold transaction and the pills switch. This seriously undermines any inference of fraudulent intent. See Druskin, 299 F. Supp. 2d at 1323 & n.25, 1326 (stating that any inference of scienter was refuted because, among other things, there were "no restatements or auditor resignations"); cf. In re Alamosa Holdings, Inc., 382 F. Supp. 2d 832, 854 (N.D. Tex. 2005) (adopting defendants' argument that allegations of fraud were insufficient "especially when [the company] has never been required to restate its financial statements").[24] In a case where the company has never restated its financial statements, it is questionable whether sufficient facts have been alleged to support a claim that GAAP was violated. And where the purported underlying GAAP violation is dubious at best, it is even more difficult to conclude that the SEC has alleged facts to support a strong inference of scienter.

[24] Under the Securities Exchange Act of 1934, auditors are required to "inform the appropriate level of the management . . . the audit committee . . . or the board of directors" if they become aware of information indicating that an illegal act has or may have occurred. 15 U.S.C. § 78j-1(b)(1)(B). If an auditor concludes that management has not taken the appropriate remedial measures, the auditor must report this conclusion to the board of directors, which is then obligated to inform the SEC of the reported illegal act. 15 U.S.C. § 78j-1(b)(2).

CONCLUSION

For the foregoing reasons, this Court should dismiss the amended complaint under Fed. R. Civ. P. 9(b) for failure to allege facts giving rise to a strong inference of scienter.

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Respectfully submitted,

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